

(g) The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

**§ 423.2014 Request for an ALJ hearing.**

(a) *Content of the request.* The request for an ALJ hearing must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following:

(1) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(2) The name, address, and telephone number of the appointed representative, as defined at § 423.560, if any.

(3) The appeals case number assigned to the appeal by the IRE, if any.

(4) The prescription drug in dispute.

(5) The plan name.

(6) The reasons the enrollee disagrees with the IRE's reconsideration.

(7) A statement of any additional evidence to be submitted and the date it will be submitted.

(8) A statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *When and where to file.* Consistent with §§ 423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration must be submitted:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration.

(2) With the entity specified in the IRE's reconsideration.

(i) If the request for hearing is timely filed with an entity other than the entity specified in the IRE's reconsideration, the deadline specified in § 423.2016 for deciding the appeal begins on the date the entity specified in the

IRE's reconsideration receives the request for hearing.

(ii) If the request for hearing is filed with an entity, other than the entity specified in the IRE's reconsideration, the ALJ hearing office must notify the appellant of the date of receipt of the request and the commencement of the adjudication timeframe.

(d) *Extension of time to request a hearing.* (1) Consistent with § 423.1972(b), if the request for hearing is not filed within 60 calendar days of receipt of the written IRE's reconsideration, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. The ALJ hearing office must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must give the reasons why the request for a hearing was not filed within the stated time period, and must be filed with the entity specified in the notice of reconsideration.

(4) If the ALJ finds there is good cause for missing the deadline, the time period for filing the hearing request will be extended. To determine whether good cause for late filing exists, the ALJ uses the standards set forth in §§ 405.942(b)(2) and (b)(3) of this chapter.

(5) If a request for hearing is not timely filed, the adjudication period in § 423.2016 begins the date the ALJ grants the request to extend the filing deadline.

**§ 423.2016 Timeframes for deciding an Appeal before an ALJ.**

(a) *Hearings.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, the ALJ must issue a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the entity

specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ grants any extension to the filing deadline.

(b) *Expedited hearings.* (1) Standard for expedited hearing. The ALJ must provide an expedited hearing decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or the ALJ determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. The ALJ may consider this standard as met if a lower level adjudicator has granted a request for an expedited hearing.

(2) Grant of a request. If the ALJ grants a request for expedited hearing, the ALJ must—

(i) Make the decision to grant an expedited hearing within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) Denial of a request. If the ALJ denies a request for expedited hearing, the ALJ must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that the ALJ will process the enrollee's request using the 90 calendar day timeframe for non-expedited ALJ hearings; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) A decision on a request for expedited hearing may not be appealed.

(5) Timeframe for adjudication. (i) If the ALJ accepts a request for expedited

hearing, the ALJ must issue a written decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the entity specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the entity specified in the IRE's reconsideration, or, if it is not timely provided, the date that the ALJ grants any extension to the filing deadline.

**§ 423.2018 Submitting evidence before the ALJ hearing.**

(a) *All hearings.* An enrollee may submit any written evidence that he or she wishes to have considered at the hearing.

(1) An ALJ will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made.

(2) An ALJ will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the coverage determination to be considered.

(b) *Non-expedited hearings.* (1) Except as provided in this paragraph, a represented enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing or within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written evidence later than 10 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received is not counted toward the adjudication deadline specified in § 423.2016.

(3) The requirements of this subsection do not apply to unrepresented enrollees.

(c) *Expedited hearings.* (1) Except as provided in this section, an enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing or